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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,856	10/20/2003	Matthew L. Tripp	68911-060	3345
7590 03/27/2006 SIMONA A. LEVI-MINZI, Ph.D. McDERMOTT WILL & EMERY LLP 201 SOUTH BISCAYNE BOULEVARD STE. 2200 MAIMI,, FL 33131			EXAMINER MELLER, MICHAEL V	
			ART UNIT 1655	PAPER NUMBER
DATE MAILED: 03/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,856

Applicant(s)

TRIPP ET AL.

Examiner

Michael V. Meller

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-213 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-213 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30, drawn to a composition, classified in class 435, subclass various.
- II. Claims 31-34, 120, drawn to a method of modulating inflammatory response in cells, classified in class 514, subclass various.
- III. Claims 35-72, 121-135, drawn to a method of treating or inhibiting a pathological condition in a mammal associated with tissue-specific activation of inflammation, classified in class 530, subclass various.
- IV. Claims 73-79, 136-140, drawn to a method of modulating the amount of cyclooxygenase-2 activity in target cells without substantially modulating COX-2 activity in non-target cells, classified in class 424, subclass various.
- V. Claims 80-101, 141-150, 179-188, drawn to a method of treating or inhibiting a pathological condition in a mammal involving inhibiting inducibility or activity of COX-2, classified in class 524, subclass various.

- VI. Claims 102-110, 151-157, 189-195, drawn to a method of inhibiting prostaglandin synthesis selectively in target cells, classified in class 935, subclass various.
- VII. Claims 111-119, 196-201, drawn to a method of inhibiting an inflammatory response selectively in target cells, classified in class 210, subclass various.
- VIII. Claim 158, drawn to a method of modulating NF-kB in cells not associated with bone resorption, classified in class 940, subclass various.
- IX. Claims 159-173, drawn to a method of treating or inhibiting a pathological condition other than osteoporosis in a mammal associated with tissue-specific activation of NF-kB, classified in class 435, subclass various.
- X. Claims 174-178, drawn to a method of modulating the amount of COX-2 activity in target cells not associated with bone resorption without substantially modulating COX-2 activity in non-target cells, classified in class 530, subclass various.
- XI. Claims 202-210, drawn to a method of treating or inhibiting inflammation other than osteoporosis in a mammal, classified in class 530, subclass various.
- XII. Claim 211, drawn to a method wherein the composition further comprises glucosamine, classified in class 514, subclass various.

XIII. Claims 212-213, drawn to a method of determining potential gastrointestinal toxicity of an anti-inflammatory agent, classified in class 424, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially distinct method such as evidenced by the claims themselves.

The different methods are restrictable from one another since they have different effects as evidenced by the claims themselves and are not capable of being used together since they are used in different applications and not together in the same process at the same time. They also have different functions from one another. Since they have different effects and functions from one another they are materially and distinct processes from one another.

The invention is drawn to many different components (first component, second component and any other component applicant wants to be in the composition) which are contained in many different compositions. The components vary distinctly in their

structures and functions. Thus, an individual search is required of each individual component. Therefore, as part of electing one of the groups as the elected invention, Applicant is also required to elect a specific composition containing specific components, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected components are drawn to. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each component is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different conditions/disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 31, 35, 73, 80, 102, 111, 120, 121, 136, 141, 151, 158, 159, 174, 179, 189, 196, 202, 211, 212 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1655

MVM